VOLUNTARY COMPLIANCE UNDERTAKING
OF
NOVARTIS PHARMACEUTICALS CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 **Product Summary**

Ciprodex®

1.1 Ciprodex® (ciprofloxacin/dexamethasone) is indicated for the treatment of infections caused by most strains of gram-positive and gram-negative microorganisms in the specific conditions including in part acute otitis media with otorrhea and acute otitis externa.

1.2 Health Canada issued a Notice of Compliance for Ciprodex® to Alcon Canada Inc. ("Alcon") on May 10, 2004. Ciprodex® was first sold in Canada on June 1, 2004.

1.3 The marketing authorization for Ciprodex® was transferred from Alcon to Novartis Pharmaceuticals Canada Inc. ("Novartis") on February 17, 2017.

1.4 The last reported patent pertaining to Ciprodex®, Canadian Patent No. 2459930, expires on September 13, 2022. Novartis is the patentee for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

Vigamox®

1.5 Vigamox® (moxifloxacin hydrochloride)is indicated for the treatment of patients one year of age and older with bacterial conjunctivitis caused by susceptible aerobic gram-positive and gram-negative bacterial strains.

1.6 Health Canada issued a Notice of Compliance for Vigamox® to Alcon on May 11, 2004. Vigamox® was first sold in Canada on June 29, 2004.

1.7 The marketing authorization for Vigamox® was transferred from Alcon to Novartis on March 24, 2017.

1.8 The last reported patent pertaining to Vigamox®, Canadian Patent No. 2342211, expires on September 29, 2019. Novartis is the patentee for the purposes of the *Patent Act* and the PMPRB.

2.0 Application of the Price *Guidelines*

2.1 The Human Drug Advisory Panel identified Ciprodex® as a Category 3 level of therapeutic improvement. The introductory National Average Transaction Prices (N-ATP) for Ciprodex® was within the thresholds set out in the *Guidelines*.

2.2 The N-ATP of Ciprodex® first exceeded its National Non-Excessive Average Price (N-NEAP) during the January to December 2017 reporting period. As of December 31, 2018, cumulative excess revenues for Ciprodex® were calculated to be $78,536.03.

2.3 Board Scientific Staff identified Vigamox® as a Category 3 level of therapeutic improvement. The introductory N-ATP for Vigamox® was also within the thresholds set out in the *Guidelines*.

2.4 The N-ATP of Vigamox® exceeded its N-NEAP during the January to December 2013 reporting period and again during the January to December 2017 reporting period. As of December 31, 2018, cumulative excess revenues for Vigamox® were calculated to be $62,623.38.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Novartis that the prices of Ciprodex® and Vigamox® are now, or were at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Novartis undertakes:

4.1.1 To agree that the 2017, 2018 and 2019 N-NEAPs for Ciprodex® and Vigamox® are as follows:

Year	Ciprodex®	Vigamox®
2017	$3.7463	$4.4443
2018	$3.7991	$4.4980
2019	$3.8503	$4.5535

4.1.2 To ensure that the 2019 N-ATPs for Ciprodex® and Vigamox® do not exceed their 2019 N-NEAPs and that the prices of Ciprodex® and Vigamox® are within the thresholds set out in the *Guidelines* in each market in which they are sold;

4.1.3 To offset the combined cumulative excess revenues accrued by Novartis in respect of Ciprodex® and Vigamox® by making a payment of $141,159.41 to Her Majesty in right of Canada within 30 days of acceptance of this VCU; and

4.1.4 To make a further payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues in respect of Ciprodex® and Vigamox® as of December 31, 2019, as calculated based on the semi-annual price and sales data filed by Novartis; and

4.1.5 To ensure that the prices of Ciprodex® and Vigamox® remain within the PMPRB's *Guidelines* in all future periods in which they are under the PMPRB's jurisdiction.

Signature: _____

Name: Lison Prévost

Position: Vice-President, Health Policy and Patient Access

Patentee: Novartis Pharmaceuticals Canada Inc.

Date: June 10, 2019_____